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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/254,590 | 05/24/1999 | JOHN P. ADELMAN | 014210-00073 | 7232 |

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EXAMINER

PAK, MICHAEL D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

DATE MAILED: 10/01/2002

LL

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/254,590

Applicant(s)
Adelman et al.

Examiner
Michael Pak

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 6, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 100-106 is/are pending in the application.
- 4a) Of the above, claim(s) 101 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 100 and 102-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5, 6 6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 6 February 2002 (Paper No.20) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/254,590 is acceptable and a CPA has been established. An action on the CPA follows.
2. Preliminary amendment filed 6 February 2002 (Paper No.21) has been entered. Claims 100-106 are pending.
3. Applicant's election with traverse of Group II, in Paper No. 21 is acknowledged. The traversal is on the ground(s) that the examination of the groups II and V together would not place an undue burden on the examiner. This is not found persuasive because the molecules are structurally different and each search requires a separate search in the separate sequence databases.

Applicant note that the genus claim is a linking claim. The examiner will take this into consideration at the time of allowance.

The requirement is still deemed proper and is therefore made FINAL.
4. Newly submitted claim 101 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Group V, claim 101, drawn to isolated nucleic acid encoding rSK2.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 101 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

It should be noted that claims 102 and 103 are drawn in part to rSK2 nucleic acid which is withdrawn in part from examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 100 and 102-106 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a nucleic acid encoding Maxi-K potassium channel and vectors comprising the polynucleotide, and cells comprising the vectors. The specification on page 5 disclose the asserted utility of identifying and using compounds which increase or decrease SK currents for use in the treatment or regulation of learning and memory disorders, seizures, myotonic dystrophies, immune responses and neurotransmitter or hormonal secretions. However, there is no nexus between the potassium channel and the treatments of the diseases. The specification as filed does not disclose or provide evidence that points to a property of the claimed

potassium channel such that another non-asserted utility would be well established. There are many different subtypes of potassium channels and no nexus has been made between the maxi K potassium channel function and the disorders listed on page 5 of the specification. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search , but compensation for its successful conclusion." Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed nucleic acid encoding the polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors and host cells do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 100 and 102-106 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Priority

6. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the continuing application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 100 and 102-106 of this application.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

8. Claims 100 and 104-106 are rejected under 35 U.S.C. 102(e) as being anticipated by Chandy et al.(US 6,165,719).

Chandy et al. disclose the nucleic acid which encodes calcium activated potassium channel which is 72% identical with claimed SEQ ID NO:19. Chandy et al. disclose the nucleic acid which encodes calcium activated potassium channel which is 88% identical with claimed degenerate nucleic acid encoding SEQ ID NO:19. Chandy et al. disclose the vectors and cells comprising the nucleic acid. The cells with the nucleic acid encoding the proteins inherently have the functional limitations because it is a calcium activated potassium channel.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael Pak
Primary Patent Examiner
Art Unit 1646
27 September 2002